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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,936	12/22/1998	Scott Miller	BAYER-0006-P01	8682
23599 7590 09/13/2011 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER KUMAR, SHAILENDRA				
ART UNIT		PAPER NUMBER		
1621				
NOTIFICATION DATE		DELIVERY MODE		
09/13/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

09/776,936

Applicant(s)

MILLER ET AL.

Examiner

SHAILENDRA KUMAR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1, 3-14, 16-19 and 21-39 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1, 3-14, 16-19, 21-35, 37 and 38 is/are allowed.
- 7) ☒ Claim(s) 36 and 39 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 297)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date: ____

DETAILED ACTION

This office action is in response to applicants' communication filed on 6/20/11.

At the outset, non final rejection filed on 8/4/10, final rejection filed 1/20/11 and advisory action filed 5/2/11, are all hereby withdrawn, AND THE FOLLOWING OFFICE ACTION IS IN ORDER.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36 and 39 are unpatentable under 35 USC 112, first paragraph, as lacking adequate written description for the claimed solvates. The claims are directed to a compound having the generic structure recited in formula I and method of treating cancer comprising a compound of formula I in a solvated form.. In both claims, there is an explicit recitation that solvates of the compounds are included in the claimed subject matter. In view of this, the solvates of the claims are viewed as a critical element of the claimed subject matter and must, therefore, be described in accordance with the requirements of 35 USC 112¹.

In the language of the physical chemist, a solvate of an organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications", Wiley, New York, 1988, pages 358 & 365. With regard to scope, the instant claims cover a wide variety of structurally divergent compounds

and place no limitation on scope of the solvent component of the claimed solvates. Thus, the claimed solvates broadly encompass interstitial solid solutions comprised of any combination of the thousands of compounds within the formula I structure with any solvent molecule that will form a solvate.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within the genus. See MPEP § 2163.

¹[The Guidelines for Written Description state “The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art” (Federal Register/ Vol. 66, No. 4/Friday, January 5, 2001/Notices, column 1, page 1105). The Guidelines further state, “[t]he claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement” (at page 1105, center column, third full paragraph). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines Inc.* (CA FC) 41 USPQ2d 1961 (at 1966).]

In the instant case, all of the teachings directed to solvates of the claimed compounds are generic and the application fails to disclose a single example of a solvate within the scope of the claims. Therefore, the application clearly fails to provide a representative number of species of the widely divergent subject matter encompassed by the claimed solvates.

Beyond the disclosure of a representative number of species, the written description requirement for a claimed genus may be satisfied through sufficient disclosure of the relevant identifying characteristics of the genus (i.e., structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics (see MPEP 2163 (ii)).

However, it is recognized in the art that the structural features of solvate compounds are highly unpredictable. For example, Jackson et al. state, “solvates, however, are notoriously unpredictable substances. One can not predict what cephalosporin compounds will form solvates, nor the solvents which solvates may be formed” (e.g., see Jackson et al., U.S. Patent No. 4,252,951, column 1, paragraph 5). This is confirmed by Braga et al. (Braga et al., “Making crystals

from crystals: a green route to crystal engineering and polymorphism” *ChemComm* **2005**, 3635-3645) who state, “while serendipitous polymorphism and solvate formation are very common ... intentional polymorphism is more difficult” (e.g., see page 3640, column 1, paragraph 1; see same paragraph, “it is extremely difficult to predict whether a new species may crystallize from solution with one or more molecules of solvent”). West (*supra*) concurs, stating in the first paragraph on page 365, “it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent”.

Viewed as a whole, the art clearly evidences that the relevant identifying characteristics of a solvate (i.e., the structural interaction of the molecules of the compound and solvent to form the interstitial solid solution) are highly unpredictable. Therefore, the description of the structure of a genus of compounds, as in the instant case, does not constitute a description of all solvates that might be formed from the compounds within that genus.

An adequate written description of a solvate requires more than a mere statement that it is part of the invention; what is required is a description of the solvate itself. It is not sufficient to define an invention solely by its principal property (i.e., it is a solvate of the disclosed compound) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any crystalline form of the disclosed compound with that property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. In view of this, the application clearly fails to describe the claimed solvates.

Applicants' arguments are moot in view of the new ground of rejection. The Examiner would like to point out that applicants agree that it is true that the prediction of what a particular solvated form, e.g., hydrate, alcoholate etc of a compound will actually look alike e.g. whether 1,2 or 3 1/2 etc, solvent molecules are incorporated, see page 3 of the Brief. Not only the form is unknown, the specification is even deprived of the word “solvate”, leave alone the making of the solvate.

Claims 1, 3-14, 16-19, 21-35 and 37-38 are free of prior art and are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Fri/5-4-9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sullivan Daniel can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Kumar
9/8/11

/SHAILENDRA KUMAR/
Primary Examiner, Art Unit 1621